



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/782,900

02/23/2004

Nelson Scarborough

00167-492001 /

5935

02-31-0466

7590

06/09/2006

Joel R. Petrow, Esq.  
Chief Patent Counsel  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, TN 38116

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,900	<b>Applicant(s)</b> SCARBOROUGH ET AL.	
	<b>Examiner</b> Andrew M. Gilbert	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 19-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/2/06, 11/12/04</u> <u>6/2/04</u>                                        | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-7, 19-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/30/2006.
2. Applicant's election with traverse of Species II in the reply filed on 5/30/2006 is acknowledged. The traversal is on the ground(s) that Species II is not mutually exclusive with Species I. This is found to be persuasive. Species I and II will be examined on the merits. Claims 8-18 stand pending with claims 1-7 and 19-36 withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

### *Drawings*

3. The drawings are objected to because numbers and lines are not uniformly thick and well defined. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

Art Unit: 3767

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Duchon et al (2003/0028144).

6. In reference to independent claim 8, Duchon et al discloses a fluid introduction system, comprising: an introducer (18; Fig 1); an operator (12); a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter ([0018]); and response data indicative of a response of the patient at a time related to a time of the fluid introduction data ([0021]). The Examiner further notes that while the injection system of Duchon et al is silent on whether the injection system can be used in the spine the injection system is Duchon et al is fully capable of being used in the spine. Further evidenced is provided by the injection system's ability to inject at

pressures up to about 1200 psi [0084] a pressure value far above the applicant's minimum desired 69 kPa (approx. 10 psi) or 100 kPa (approx 14.5 psi).

7. In reference to claim 9, Duchon et al additionally discloses wherein the fluid introduction parameter is a pressure within an intervertebral disc of the patient at the time of the fluid introduction data ([0020]).

8. In reference to claim 10, Duchon et al additionally discloses wherein the fluid introduction parameter is a total amount of fluid introduced into an intervertebral disc of the patient at the time of the fluid introduction data ([0020]).

9. In reference to claim 11, Duchon et al additionally discloses wherein the fluid introduction system is configured to obtain the response data upon a response by the patient ([0020], [0021]).

10. In reference to claim 12, Duchon et al additionally discloses wherein the fluid introduction system is configured to obtain the response data from an observation of the patient ([0020], [0021]).

11. In reference to independent claim 14, Duchon et al discloses an introducer (18; Fig 1) configured to introduce a non-pulsatile flow of fluid into a spine, the introducer having a flow rate-dependent impedance (104) opposing the introduction of the fluid; and an operator (12) configured to actuate the introducer, the operator including code [100] to control the actuation of the introducer based at least in part upon impedance data indicative of the impedance ([0121]).

Art Unit: 3767

12. In reference to claim 15, Duchon et al additionally discloses wherein the introducer includes an identifier (114) including the impedance data and the operator is configured to receive the impedance data from the identifier of the introducer ([0121]).

13. In reference to claim 16, Duchon et al additionally discloses wherein the operator includes code to determine the impedance data based upon an actuation of the introducer ([0120]).

14. In reference to claim 17, Duchon et al additionally discloses a pressure sensor (114) configured to provide pressure data indicative of a pressure of fluid present in the introducer ([0121]); a fluid introduction sensor (108, 110, [0120]) configured to provide fluid introduction data indicative of at least one of (a) a rate of fluid introduction and (b) an amount of fluid introduced ([0120]); and wherein the operator includes code to determine the impedance data based upon the pressure data and the fluid introduction data ([0120]).

15. In reference to claim 13 and 18, Duchon et al additionally discloses wherein the introducer is configured to create a pressure of at least 69 or 100 kPa within the spine (0005), [0084]).

16. The Examiner further directs the Applicant to the Summary of the Invention ([0012]-[0022]) and the Specification ([0155]-[0185]) for a further discussion of the functioning of the operator of Duchon et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)

Art Unit: 3767

272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN SIRMONS  
PRIMARY EXAMINER

